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Date November 26, 2003

To Examiner Susan D. Coe  
U.S. Patent & Trademark Office  
Commissioner for Patents  
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From Y. Rocky Tsao

Re Anti-ulcer pharmaceutical composition and the preparation thereof

Applicant: Feng-Nien Ko et al.

Application No.: 09/522,434

Filing Date: March 9, 2000

Our Ref.: 11544-003001

Number of pages  
including this page 3

Message Please hand deliver to Examiner Susan Coe. Thanks.

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## FISH &amp; RICHARDSON P.C.

Frederick P. Fish  
1855-1930

W.K. Richardson  
1859-1951

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Re: ANTI-ULCER PHARMACEUTICAL COMPOSITION AND THE PREPARATION THEREOF

Applicant: Feng-Nien Ko et al.  
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Dear Examiner Coe:

Thank you for granting a telephone interview, scheduled for 2:30 pm, December 1, 2003 to resolve issues raised in the final office action. This letter is limited to claim 1 to facilitate discussion.

1. Claim 1 was rejected as being anticipated by U.S Patent NO. 4,317,816. It covers a pharmaceutical composition that contains an American ginseng extract prepared by a specific process. In the response filed August 6, 2003, we pointed out that the extract has ether-soluble components that are not present in the extract taught in the '816 patent. You countered that "ether-soluble components" was not recited. Note that the specific process recited in claim 1 is essentially closed ended. See the recitation "consists essentially of." In other words, it does not include other steps, e.g., ether precipitation taught in the '816 patent. Accordingly, the American ginseng extract recited in claim 1 inherently contains ether-soluble components and therefore differs from that in the '816 patent.

2. You also rejected claim 1 as being anticipated by JP 04316507 and JP 61109732. These two references teach American ginseng extracts that contain compounds having molecular weights of greater than 10,000 and 100,000, respectively. It appears to be your position that, since claim 1 recites the phrase "at least 1,000," the term "ginseng extract" recited in claim 1 covers the prior art extracts. This phrase was added to the claim to indicate that the extract recited in claim 1 contains compounds that have molecule weights of greater than 1,000.

In this connection, we would like to point out that an American ginseng extract contains many compounds having molecular weights of between 1,000 and 10,000. See Yoshikawa *et al.* (*Chem. Pharm. Bull.* 46(4): 647-654, 1998), which was presented with our response filed on December 11, 2002. In other words, the extract recited in claim 1 inherently contains compounds having molecular weights of between 1,000 and 10,000. Since the ginseng extracts taught in JP 04316507 and JP 61109732 do not contain these compounds,

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the composition of claim 1 is novel. In any event, for the sole purpose of moving this case toward allowance, we propose amending claim 1 as follows:

1. (Currently amended) A pharmaceutical composition for preventing or treating peptic ulcer, comprising:

(i) an American ginseng extract in an amount effective for preventing or treating peptic ulcer; and

(ii) a pharmaceutically acceptable carrier;

wherein said American ginseng extract consists essentially of a preparation obtained by extraction with a solvent, centrifugation, and filtration through an ultrafiltration membrane ~~with molecular weight cut off~~ at least 1,000 to give a retentate, and concentration of the retentate, and

wherein the retentate contains compounds having molecular weights of at least 1,000 dalton.

This amendment is supported by the specification (see page 7, lines 2-5) and does not necessitate a new search.

We look forward to discussing with you the above issues at the interview.

Very truly yours,



Rocky Tsao, Ph.D., J.D.  
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